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Technical Position on Items and Activities in the High-Level Waste Geologic Repository Program Subject to Quality Assurance Requirements

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

A.B. Duncan, S.G. Bilhorn, and J.E. Kennedy

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ABSTRACT

This document provides guidance on how to identify items and activities subject to Quality Assurance in the high-level nuclear waste repository program for pre-closure and post-closure phases of the repository. In the pre-closure phase, structures, systems, and components essential to the prevention or mitigation of a accident that could result in an off-site radiation dose of 0.5rem or greater are termed "important to safety". In the post-closure phase, the barriers which are relied on to meet the containment and isolation requirements are defined as "important to waste isolation". These structures, systems, components, and barriers, and the activities related to their characterization, design, construction, and operation are required to meet quality assurance (QA) criteria to provide confidence in the performance of the geologic repository. The list of structures, systems, and components important to safety and engineered barriers important to waste isolation is referred to as the "Q-List" and lies within the scope of the QA program.

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1.0 INTRODUCTION

The requirements which apply to protection of public health and safety and the environment from disposal of high-level radioactive waste (HLW) in a geologic repository are defined in 10 CFR Part 60. These requirements address a pre-closure phase, which includes design, construction, waste emplacement, and possible retrieval of waste, and a post-closure phase, which includes containment and long-term isolation of waste. In the pre-closure phase, structures, systems, and components essential to the prevention or mitigation of an accident that could result in an off-site radiation dose of 0.5 rem or greater are termed "important to safety" (10 CFR 60.2). In the post-closure phase, the barriers which are relied on to meet the containment and isolation requirements of 10 CFR Part 60 are defined as "important to waste isolation." These structures, systems, components, and barriers (items), and the activities related to their characterization, design, construction, and operation are required to meet quality assurance (QA) criteria to provide confidence in the performance of the geologic repository. The list of structures, systems, and components important to safety and engineered barriers important to waste isolation is referred to as the "Q-list" and lies within the scope of the QA program specified in 10 CFR Part 60 Subpart G.

In order to obtain a license for a geologic repository, the U.S. Department of Energy (DOE) must demonstrate that all of the requirements in 10 CFR Part 60 are met. To help provide this demonstration, DOE is required to implement a QA program for verifying and documenting the quality of work performed to support licensing findings. The purpose of this Technical Position (TP) is to provide NRC staff positions on QA criteria for licensing, the types of analyses appropriate to determine which items and activities are important to safety and/or waste isolation, the staff information needs to assure adequate and timely staff involvement, and the graded application of quality assurance measures to items and activities important to safety and/or waste isolation.

2.0 REGULATORY BACKGROUND

The identification of items with safety significance has been an important issue in the nuclear power reactor program. It has been the subject of litigation in various reactor licensing hearings and has been the cause, in part, for extensive delays in schedules and large increases in cost for reactor plant construction. In the reactor program, safety-related items are subject to the QA program requirements in 10 CFR 50 Appendix B. These items comprise the reactor list of quality components or "Q-list." Through reactor licensing experience the NRC has developed a body of practice which can be used to help determine which items are on the Q-list for a specific power plant. This body of practice includes, for example, a series of design basis accidents, a source term for release of radionuclides to the atmosphere, and meteorological conditions to be assumed during an accident. Listings of safety-related items also have been developed at the system level based on years of staff and industry experience with nuclear power reactors.

In contrast to the reactor program where fairly prescriptive criteria have been developed, the principal criteria for identifying the Q-list for a geologic

repository are broad performance objectives. In the pre-closure phase of the repository, structures, systems, and components important to safety are those items essential to the prevention or mitigation of an accident causing an off-site dose of 0.5 rem or greater. There are no explicit design basis accidents, source terms for releases, meteorologic conditions, or generic lists of items identified in the requirements or guidance. DOE, therefore, has flexibility in developing approaches for establishing this information. For post-closure, 10 CFR Part 60 also provides DOE some flexibility in determining which specific barriers will be relied upon to meet each performance objective.

To help ensure protection of radiological health and safety of the public and the environment, 10 CFR 60 Subpart G requires that DOE apply a QA program to "all systems, structures and components important to safety, to design and characterization of barriers important to waste isolation and to activities related thereto" (10 CFR 60.151). DOE is required to provide a description of the 10 CFR 60 Subpart G QA program in the Safety Analysis Report provided with the license application (10 CFR 60.21(c)(4)). Staff guidance on the 10 CFR 60 Subpart G QA program is contained in the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Waste Repositories" (USNRC, 1984).

Structures, systems, and components important to safety are those items essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure (10 CFR 60.2). The overall system performance objective for a geologic repository following permanent closure specifies that the geologic setting be selected and the engineered barrier system, shafts, boreholes, and their seals be designed to assure that releases of radioactive materials to the accessible environment conform to the environmental standards established by the Environmental Protection Agency (40 CFR Part 191), as incorporated into 10 CFR 60.112. The performance objectives for certain barriers after permanent closure are specified in 10 CFR 60.113 and include a 1000 year groundwater travel time and a 300-1000 year waste package lifetime. The barriers and activities that are relied on to meet the specific and overall containment and isolation requirements of 10 CFR 60.112 and 60.113 are considered "important to waste isolation."

In addition to items and activities important to safety and/or waste isolation, other items and activities will be associated with assuring that DOE meets all of the 10 CFR Part 60 licensing requirements. For example, 10 CFR Part 20 requirements, which are referenced in 10 CFR Part 60, are to be addressed in the license application, and confidence needs to be established in the work associated with these requirements.

3.0 DEFINITIONS

This section provides definitions of significant terms used in the staff positions presented in this TP. Definitions for other commonly used terms are provided in Appendix A, the Glossary.

Activities: Deeds, actions, work, or performance of a specific function or task. In the HLW geologic repository program, the 10 CFR Part 60 Subpart G QA

program applies to activities affecting the quality of all systems, structures, and components important to safety, and to the design and characterization of barriers important to waste isolation. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities as they relate to items important to safety and barriers important to waste isolation (10 CFR 60.151). In addition, the pertinent requirements of 10 CFR Part 50 Appendix B apply to all activities affecting the quality of structures, systems, and components important to safety and engineered barriers important to waste isolation. These activities include: designing (including such activities as safety analyses, laboratory testing of waste package materials to characterize their performance, and performance assessments), purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, and modifying. These types of activities do not need to be identified as part of the Q-List or Quality Activities List. However, activities related to natural barriers important to waste isolation should be identified and listed on a Quality Activities List. These activities include: performance assessments, site characterization testing, and activities that may impact the waste isolation capability of the natural barrier. For example, site characterization activities such as exploratory shaft construction, borehole drilling, and other activities that could physically or chemically alter properties of the natural barriers in an adverse way.

Barrier: Any material or structure that prevents or substantially delays movement of water or radionuclides (10 CFR 60.2).

Credible event or credible accident: An event or accident scenario which needs to be considered in the design of the geologic repository.

Items important to safety: Those engineered structures, systems, and components essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure (10 CFR 60.2).

Items important to waste isolation: Natural and engineered barriers which are relied on for achieving the postclosure performance objectives in 10 CFR 60 Subpart E.

Q-list: In the geologic repository program, a list of structures, systems, and components important to safety, and engineered barriers important to waste isolation that must be covered under the QA requirements of 10 CFR 60 Subpart G.

Quality Activities List: In the geologic repository program, a list of those major activities conducted during site characterization, construction, operation, or closure that relate to natural barriers important to waste isolation. These activities, which must be covered under the 10 CFR Part 60 Subpart G QA program, include data gathering, performance assessments, and those activities that could affect a natural barrier's ability to isolate waste.

4.0 STAFF POSITIONS

4.1 Quality Assurance Criteria for Licensing

(a) Criteria for the Q-list and Quality Activities List

DOE shall apply a QA program which meets the 10 CFR 60 Subpart G requirements to all systems, structures, and components important to safety, barriers important to waste isolation, and related activities (10 CFR 60.151).

(b) Criteria for Non-Q-list Items

In addition to criteria for items and activities important to safety and/or waste isolation, 10 CFR Part 60 contains requirements for other items and activities, such as those associated with meeting the design criteria contained in 10 CFR 60.131(a) for protection of worker health and safety. While these items and activities are not subject to the QA requirements in 10 CFR 60 Subpart G, DOE should implement a program to assure compliance with those aspects of 10 CFR 60 which apply to items other than those important to safety and/or waste isolation.

(c) Data Not Collected Under 10 CFR 60 Subpart G QA Program

Data developed prior to the implementation of a 10 CFR 60, Subpart G QA program by DOE and its contractors, or data developed outside the DOE repository program, such as by oil companies, national laboratories, universities, or data published in technical or scientific publications should be evaluated to determine its suitability for use in licensing. Staff guidance on methods for qualifying these data is provided in the "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories," (USNRC, 1987).

4.2 Identification of Items Important to Safety

All engineered structures, systems, and components essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure shall be on the Q-list. The frequency of occurrence and consequences of accident sequences should be analyzed to determine the accident sequences that should be considered in the identification of items important to safety. In general, in identifying items important to safety, DOE should include all accident sequences whose occurrence is deemed sufficiently likely to warrant consideration. However, the staff anticipates that the DOE evaluation of potential accidents could also identify a range of accidents with a very low frequency of occurrence but whose dose consequences are sufficiently high to warrant consideration in establishing the Q-list. DOE should also consider these low probability/high consequence accidents in establishing the Q-list.

However, this is not to say that DOE must consider all high consequence accidents in establishing the Q-list, no matter what the probability of occurrence. Accidents of an extremely low probability need not be considered in establishing the Q-list. The NRC staff will review the DOE evaluation of accident probabilities and consequences to determine whether the selection of accidents for the establishment of the Q-list was appropriate.

Structures, systems, or components whose failure may initiate an accident which results in a dose of 0.5 rem or greater should not be removed from the Q-list due to the addition of mitigating features. In cases where the failure of an item is deemed to be incredible and therefore need not have additional features installed to mitigate the consequences of its failure, justification such as reliability data, design margins, and in-service and qualification testing should be developed.

DOE should use a systematic analysis to identify items important to safety. These analyses should identify external and internal initiating events and scenarios, analyse the response of safety systems to these events and scenarios, and calculate the offsite dose consequences.

(a) Analysis

DOE may use probabilistic risk assessment (PRA) techniques, to the extent practicable, to support the identification of structures, systems, and components important to safety. Probabilities of scenarios and releases will need to be developed. However, there are and may continue to be few data sources available on the reliability of items unique to the repository but nonetheless necessary to support detailed risk assessments. Therefore, engineering judgment and conservative bounding assumptions may be made and should be justified to assure that credible accidents will be prevented and/or mitigated as required to protect public health and safety.

Operator actions or errors which could initiate or aggravate accidents should also be identified in PRAs or other safety assessments.

(b) Redundancy

DOE shall, as a minimum, employ redundancy in those areas specified in 10 CFR Part 60 [i.e., 10 CFR 60.131(b)(5)(ii)]. Systems, structures, and components important to safety used to provide redundancy shall be included on the Q-list.

(c) Use of Previously Established Guidelines and Standards

DOE may utilize existing nuclear facility guidelines and standards for initiating events (e.g., Regulatory Guides covering the design basis earthquakes, tornado wind velocities, and floods) in the identification of items important to safety where

these criteria can be shown to be applicable to the geologic repository.

(d) Retrieval

In the event that retrieval is necessary, DOE should, at that time, analyze the proposed retrieval process to identify additional items that are important to safety. These additional items should also be covered under the Subpart G QA Program.

4.3 Identification of Items and Activities Important to Waste Isolation

Items important to waste isolation should include those engineered and natural barriers which are relied on to meet the post-closure performance objectives of the repository system. DOE should allocate performance among the various components of the natural and engineered barrier systems to provide a basis for determining which items may be important to waste isolation. Those engineered barriers important to waste isolation should be placed on the Q-list.

Those site characterization activities which potentially will provide data to be relied on in performance assessments of the waste isolation and containment capabilities of natural and engineered barriers, those activities related to the actual performance assessments, and those activities that may adversely impact the waste isolation capabilities of these barriers should be controlled under a Subpart G QA program. Activities should be identified in the Quality Activities List as described in Section 5.3.

4.4 Staff Information Needs

(a) License Application

DOE shall submit with the license application a description of the QA program to be applied to items important to safety and/or waste isolation [10 CFR 60.21(c)(4)]. DOE shall identify the structures, systems, and components important to safety [10 CFR 60.21(c)(1)(ii)(E) and 60.21(c)(3)], and describe the analyses used in this identification. DOE should also identify the barriers important to waste isolation falling under the 10 CFR 60 Subpart G QA program and describe the evaluations used to identify these barriers [10 CFR 60.21(c)(1)(ii)(C)]. A Quality Activities List, as defined in Section 3.0, should also be provided listing major site characterization, construction, operation, and performance confirmation activities under the QA program.

(b) Site Characterization Plans

The following information related to the Q-list should be submitted in the Site Characterization Plan:

- A description of the QA program to be applied to items and activities during the site characterization phase.

- o A preliminary Q-list identifying major structures, systems, and components important to safety, engineered barriers important to waste isolation and the methodology used to develop the list.

- o A list of major site characterization activities (Quality Activities List) and the QA requirements which apply to them.

- o A general description of the process by which the preliminary Q-list will be revised as the design advances.

Plans for development and implementation of a QA program to demonstrate that non-Q-list licensing requirements are met should also be described in the Site Characterization Plan.

4.5 Graded Application of QA Measures

The 10 CFR 60 Subpart G requirements can be met using graded QA measures and should be applied to items and activities important to safety and/or waste isolation based on considerations such as the following:

- o The impact of malfunction or failure of the item, or the impact of erroneous data associated with data collection activities, on safety or waste isolation.

- o The complexity of design or fabrication of an item, or design and implementation of a test, or the uniqueness of an item or test.

- o The special controls and surveillance needed over processes, tests, and equipment.

- o The degree to which functional compliance can be demonstrated by inspection or test.

- o The quality history and degree of standardization of the item or test.

5.0 DISCUSSION

This discussion section provides the rationale for and amplification of the positions in Section 4.0 and is organized to follow the same headings.

5.1 Quality Assurance Criteria for Licensing

The purpose of the geologic repository program is to permanently dispose of high-level nuclear waste. In order to obtain a license for receipt and possession of radioactive material at the geologic repository, the DOE must demonstrate that the repository system will function as required to protect health and safety of the public and the environment. Requirements for licensing a repository to meet this goal are specified in 10 CFR Part 60. These requirements

describe the performance objectives and other technical criteria to assure safe operation during waste emplacement and retrieval (if necessary), as well as effective containment and longterm isolation of waste following permanent closure of the geologic repository. 10 CFR 60 Subpart G specifies the QA program for these items and related activities important to safety and/or waste isolation to assure that their characterization, design, construction, and operation comply with the requirements of 10 CFR Part 60.

(a) Criteria for the Q-List and Quality Activities List

The 10 CFR 60 Subpart G QA program applies to items and activities important to safety and/or waste isolation. As derived from 10 CFR Part 60 (60.152), this QA program is based on the 18 criteria of 10 CFR Part 50 Appendix B. These criteria address, in general terms, the basic elements of a QA program, such as organization, design control, test control, inspection, and records management. As noted in 10 CFR 60.152, these criteria may be supplemented as necessary to meet the specific requirements of the repository program. NRC staff guidance on the application of the Appendix B QA criteria to the site characterization phase of the repository program is provided in the "NRC Review Plan: Quality Assurance Programs for Site Characterization of High Level Nuclear Waste Facilities," (USNRC, 1984).

In addition to the QA requirements in 10 CFR 60 Subpart G, items important to safety and the waste package are subject to the design criteria of 10 CFR 60.131(b) and 60.135 respectively. These added criteria help to provide assurance that the margins of safety are adequate throughout the life of the facility and the waste package. They include protection of items important to safety from natural phenomena and environmental conditions, dynamic effects of equipment failure, and fires and explosions, as well as criteria for special emergency capabilities, criticality control, and shaft conveyance features.

(b) Criteria for Non-Q-list Items

Certain items that are not important to safety and/or waste isolation must also be addressed in the license application to demonstrate compliance with 10 CFR Part 60 requirements. While these items are not subject to the QA requirements in 10 CFR 60 Subpart G, DOE should implement a program to provide adequate confidence that these requirements are met. These items will be encompassed in NRC staff review of the DOE license application for a HLW repository.

One example of NRC guidance for QA programs during normal operations is addressed in Regulatory Guide 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment" (USNRC, 1979).

(c) Data Not Collected Under 10 CFR 60 Subpart G QA

All data collection, interpretations, analyses, and other work to be used to support findings related to important to safety and/or waste isolation in the licensing process must be technically and procedurally defensible by the DOE. The staff expects that some information collected outside the 10 CFR 60 Subpart G QA program, termed "existing data" may be used or referenced by DOE in the licensing process for items and activities important to safety and/or waste isolation. Such data may have been generated by sources such as oil companies, university research programs, and DOE or DOE contractors prior to implementation of a 10 CFR 60 Subpart G QA program. DOE should review the quality and traceability of existing data to determine whether it can be qualified for licensing.

The staff has developed a position paper entitled "Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories" (USNRC, 1987), which provides guidance to DOE on what the staff considers appropriate methods of qualifying existing data for potential use in licensing. DOE should use this guidance in the development of programs for qualifying existing data.

In addition to existing data, some materials that may be important to safety and/or waste isolation may already have been purchased prior to implementation of a 10 CFR 60 Subpart G QA program. DOE needs to review the supporting documentation on these materials (e.g. the technical specifications and QA records) to determine whether they meet the technical and QA requirements for their designated function. If not, DOE will need to "qualify" them for use to assure they will perform their intended function. Some methods recommended for qualification of existing data (such as confirmatory testing) may also be applied to qualify the existing materials and their supporting data (see the staff position paper referenced above).

5.2 Identification of Items Important To Safety

Items important to safety are those items essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure (10 CFR 60.2). The 0.5 rem value is, therefore, the threshold for determining what structures, systems, and components shall be on the Q-list as items important to safety. The rationale for placing a system, structure, or component on the Q-list is to provide added assurance, via application of rigorous QA/QC and design requirements, that they should perform their designated function.

(a) Analysis

DOE may use PRAs, to the extent practicable, to support the identification of structures, systems, and components important to safety in the license application. PRAs have been shown to be a useful design tool for systematically evaluating the safety of nuclear facilities. In addition, use of this approach for the operations phase of the program is consistent with the approach prescribed by the EPA standard (40 CFR Part 191) for the overall system containment following emplacement of waste in a geologic repository. In cases where data are limited, engineering judgment and conservative bounding assumptions will need to be used. Conservative assumptions may include non-mechanistic failures where information and/or experience are not adequate to reliably determine failure modes and accident scenarios. However, non-mechanistic failures need not be considered where failure modes and mechanisms are understood and failure rates can be determined.

Operator actions or errors which could initiate accidents should be identified in PRA's or other analysis. These should be controlled to minimize the probability of occurrence. Other activities which are under the QA program, such as designing, inspecting, and purchasing will not be identified in PRA's but will need to be controlled under the QA Program.

PRA's utilize the following techniques:

(1) System modeling to depict the combination of safety function and system successes or failures which constitute accident scenarios. Two modeling techniques often used are event tree analysis, which identifies the sequence of events that may result in an accident, and fault tree analysis, which determines how failures in safety systems may occur. Both techniques are analytical tools which organize and characterize potential accidents in a methodical manner.

    An event-tree defines a comprehensive set of accident sequences that encompasses the effects of all realistic and physically possible potential accidents. By definition, an initiating event is the beginning point in the sequence. Hence, a comprehensive list of accident-initiating events must be compiled to ensure that the event trees properly depict all important sequences.

    A fault tree examines the various ways in which a system designed to perform a safety function can fail. Each safety system identified in the event tree as involved in an accident is examined to determine how failures of components within that system could cause the failure of the entire system.

    If failure of a mitigating system could contribute to an off-site dose, individual components within the mitigating system need to be reviewed, using fault tree analysis, to

determine the effect of their failure on performance of the overall system. For example, individual components in the ventilation system which may need to be analyzed include dampers, motors, and filters.

(2) Consequence analysis of accident scenarios identified in event/fault tree analyses to determine the amount and kind of radionuclides which may reach the unrestricted area and contribute to an off-site dose. Consequence analysis includes identification of a source term for radioactive releases and evaluation of mechanisms for movement and deposition of radioactive materials released from the HLW facility. The energy, magnitude, and timing of radiological releases resulting from various accidents need to be considered in this analysis.

(3) Analysis to assess the effect of uncertainties in the data base and uncertainties arising from modeling assumptions on the PRA findings. The insights gained in the analysis about features that are significant contributors to risk can provide qualitative understanding into system performance.

The NRC Office of Nuclear Regulatory Research has an ongoing study for assessing pre-closure accidents. The latest report published under this study (Harris, et al., 1985) contains examples of initiating events, accident scenarios, and discussions of possible consequences using a specific design for a HLW facility.

(b) Redundancy

The use of redundant structures, systems, and components is a method of providing additional assurance that necessary safety functions will be performed if an accident occurs and that the accident dose limit will not be exceeded. In a redundant system, the failure of one train of the system should not compromise or prevent the associated safety function from being performed. For the high-level waste repository, 10 CFR 60 [60.131(b)(5)(ii)] addresses requirements for redundancy. The items needed to provide redundancy for items important to safety shall also be on the Q-list.

(c) Use of Previously Established Guidelines and Standards

Many guidelines and standards have been developed in the nuclear power reactor program and other nuclear programs which may be applicable for the geologic repository program. For example, there are regulatory guides covering design basis earthquakes, floods, and tornado wind velocities which may be used in the the design of the HLW facility and developing the Q-list. While some of these guidelines and standards may not be directly applicable to a geologic repository, DOE should consider their use, to the extent practicable, to eliminate the need to develop

new approaches. NRC staff will review these guidelines and standards proposed by DOE.

(d) Retrieval

The option for retrieval of waste is addressed as a performance objective in 10 CFR 60.111(b). If retrieval is found to be necessary, analyses of retrieval operations need to be conducted by DOE, at that time, to identify Q-list items.

5.3 Identification of Items and Activities Important to Waste Isolation

The term "important to waste isolation" refers to engineered and natural barriers that will be relied on to meet the containment and isolation performance objectives of 10 CFR 60 Subpart E. Four of the performance objectives for waste isolation after permanent closure are stated in 10 CFR 60.112 and 60.113 and include:

- ground water travel time
- waste package containment period
- maximum yearly release rate from the engineered barrier system
- the overall system performance objective in 10 CFR 60.112 for release of radioactive materials to the accessible environment (the EPA standard in 40 CFR Part 191).

The items and activities important to waste isolation should include:

- components of the engineered barrier system relied on to meet the performance objectives.
- elements of the natural barrier system (e.g., host rock, and geochemical retardation characteristics) relied on to meet the performance objectives.
- activities necessary to demonstrate that the performance objectives will be met, including collection of data to characterize the site or performance of engineered barriers, and
- activities in the preclosure phase that could affect post-closure performance.

The broad performance objectives for waste isolation provide DOE with some flexibility in allocating credit among the various components of the natural and engineered barrier systems to meet each objective. For example, a 300 to 1000 year lifetime for the waste package might be achieved by a combination of performance from each of the components in the waste package or by a single component, such as the canister. The allocation of performance among the various components of the natural and engineered barrier system for each performance objective will provide the basis for determining which barriers are important to waste isolation. Performance assessments shall be conducted on these barriers to ascertain that those relied on will meet the waste isolation and containment performance objectives of

10 CFR Part 60. The initial allocations of performance will provide a basis for determining what site characterization testing will be needed. The initial allocation of performance among the barriers is likely to change based on the results of performance assessments using data collected during site characterization.

It is expected that most of the data collected during the site characterization phase can potentially be used in the license application performance assessments. During the early phase of characterization in particular, when little is known about the site and the importance of data characterizing it, most data collection activities should be controlled under Subpart G. However, there may be cases where it is known that data are not needed for performance assessments, or will be duplicated under Subpart G and therefore would not have to be covered under Subpart G. For example, scoping tests or tests to examine the feasibility and appropriateness of a data collection technique may not need to be performed under Subpart G.

5.4 Staff Information Needs

(a) License Application

Items and activities within the scope of the 10 CFR Part 60 Subpart G QA program should be identified in the license application. The staff positions in Section 4.4 state that at the time of the license application, DOE should provide the list of items important to safety and waste isolation, a description of the analyses used to identify these items, a Quality Activities List, and a description of the QA program to be applied to these items and activities. This information will be used by the staff in making the findings required to issue a construction authorization.

(b) Site Characterization Plan

Prior to submission of the license application, DOE is required to submit a site characterization plan (SCP). In order for the NRC staff to identify licensing issues early so that they may be resolved prior to the license application, the methodology for determining the scope of items important to safety and/or waste isolation, a preliminary Q-list, a Quality Activities List and a description of the 10 CFR 60 Subpart G QA Program applicable to items and activities for the site characterization phase should be provided in the SCP. The preliminary Q-list should include items important to safety and/or waste isolation and should be supported by conservative analyses to assure all potential items are identified at least at the system and major component level. The Quality Activities List should include major site characterization activities. As the design matures and more information is collected, items and activities may be removed from or added to the Q-list or Quality Activities List. These additions and deletions should be highlighted in the semi-annual update of the SCP. Changes of this type are expected and should be documented

with supporting analysis and rationale. The process for refinement of the preliminary Q-list and Quality Activities List based on design advancements, data collection and analyses should be identified in the SCP to support the staff's evaluation of the QA plans. The staff will periodically review the process for making additions or deletions from the lists to assure that it is adequate and reliable rather than review every change to the lists.

5.5 Graded Application of QA Measures

Adequate confidence in the quality of the items and activities within the scope of the QA program, may be obtained with graded QA measures. This flexibility is provided in 10 CFR 60 Subpart G through reference to 10 CFR 50 Appendix B. Criterion II of Appendix B states that the QA program shall provide for control over activities affecting the quality of structures, systems, and components to an extent consistent with their importance to safety. It is expected that safety analyses can provide evaluations of the importance to safety and/or waste isolation of particular structures, systems, or components. These evaluations can then provide a logical framework for application of graded QA measures.

NQA-1 (ANSI/ASME, 1986) is a consensus standard which provides more detailed guidance on grading QA for nuclear facilities. NQA-1 Appendix 4A-1 Section 5.0 contains criteria for grading QA measures, which have been modified as follows in this TP for use in the repository program.

- The impact of malfunction or failure of the item on safety or waste isolation or the impact of erroneous data associated with data collection activities, important to safety and/or waste isolation. For example, components may play a major role in safety, perform supporting functions for primary equipment, perform redundant functions (i.e., two items may perform identical functions but only one may be needed to prevent or mitigate an accident), or perform functions for low consequence events or accidents with very low probabilities of occurrence. Likewise, data will vary in degrees of importance to safety or waste isolation. PRAs can provide a framework for grading of QA measures based on the risk associated with the failure of individual components.

- The complexity of design or fabrication of an item, or design and implementation of a test, or uniqueness of the item or test. Complex items or tests may require extensive design efforts or extensive inspection or peer review during their development to assure satisfactory results.

- The special controls and surveillance needed over special processes, tests,and equipment. Special processes and equipment which affect the quality of components, data or analyses and whose effects on the components, data or analyses cannot be easily measured or evaluated in the final product, such as

welding and heat treatment, shall be controlled as prescribed by Criterion IX of 10 CFR 50 Appendix B.

- The degree to which functional compliance can be demonstrated by inspection or test. Proof of the quality of a component can sometimes be demonstrated by inspection and/or testing of a final product. In such cases, the in-process control program may be reduced. The limiting case is whether an end product test can properly assess the degree of compliance to quality requirements and thereby eliminate the need for in-process control.

- The quality history and degree of standardization of the item or test. If a manufacturer or organization has been producing a particular standard item or conducting a standard test for a long period and if the quality history of the item or test indicates acceptable performance, QA measures may be tailored to that item or test to reflect the demonstrated performance. Conversely, if certain characteristics are determined to be unsatisfactory based on operational data, additional QA measures may be required to assure that experienced deficiencies are identified and corrected or controlled.

In implementing the above guidance for items important to safety and/or waste isolation, the amount and types of inspection, testing, and recordkeeping are the primary areas to be graded.

For items and activities important to waste isolation, QA measures should not be significantly graded based on their importance to waste isolation in the early phases of site characterization. The characteristics of individual components or phenomena of the natural or engineered systems are not well known prior to extensive data collection and analysis and their contribution to meeting the numerical performance objectives of 10 CFR Part 60 cannot be confidently established at that time. A conservative level of QA should be applied to testing and design of barriers in the event that subsequent data analyses show them to be important in meeting the isolation and containment requirements of 10 CFR Part 60. Some flexibility in this approach may be permitted if conservative performance goals are established for individual components or phenomena and for routine or simple tests or components. The following example of how grading can be accomplished is helpful in interpreting the guidance given above.

During the field investigations, the amount of inspection and control that is placed on the various activities may vary due to the complexity of the tests and the amount and importance of the information to be collected. If, for example, a boring is planned for the sole purpose of obtaining an additional ground water level measurement to confirm existing gradients, it may not be necessary to place a large number of controls on the drilling of this boring; for example, a full-time inspector may not be required to observe the drilling. If, on the other hand, the purpose of the boring was to obtain accurate measurements of the orientation of joints and

fractures, and to obtain ground water samples for chemical analysis, the controls which should be imposed would be more stringent. The drilling rig may need to be inspected prior to operation to assure that the appropriate equipment and procedures were in place to achieve the desired objective. Any drilling fluid introduced into the hole would likely be analyzed and have a tracer added, and controls might be placed on the types of additives which could be used in the hole. In this example, it would be likely that a full-time inspector would be on the drill site to assure that all procedures were followed and documentation completed. Boring completion and testing of this hole should be documented in a detailed series of field reports. In both cases, the NRC staff would expect documentation showing that information was obtained correctly. However, the level of effort would be considerably different for these two situations.

6.0 SUMMARY

This TP provides guidance on approaches the staff considers acceptable for identifying items and activities within the scope of the 10 CFR 60 Subpart G QA program. It also gives guidance on how to apply QA to these and other items and activities in order to demonstrate compliance with the requirements of 10 CFR Part 60. DOE may use PRA techniques, to the extent practicable, to identify items important to safety. DOE should identify barriers important to waste isolation based on performance allocation and performance assessments. The final Q-list and Quality Activities List should be contained in the description of the 10 CFR 60 Subpart G QA program included in the license application and a provisional Q-list and Quality Activities List should be presented in the SCP. The provisional Q-list should be based on available data, engineering judgment, and conservative assumptions. In addition to addressing items on the Q-list, DOE should apply an appropriate level of QA to non-Q-list items that will be needed to support other licensing requirements, such as those in 10 CFR 60.131 for radiological protection of workers. DOE may apply graded QA measures to items on the Q-list based on the criteria in NQA-1 Appendix 4A-1 (ANSI/ASME, 1986) when information is available to support such grading.

7.0 REFERENCES

American Nuclear Society (ANS) and Institute of Electrical and Electronics Engineers (IEEE). 1983. PRA Procedures Guide, NUREG/CR-2300, Washington, DC.

American Society of Mechanical Engineers (ASME). 1986. Quality Assurance Program Requirements for Nuclear Facilities, ANSI/ASME NQA-1, New York, NY.

Harris, P.A., D.M. Ligon, M.G. Stamatelatos. 1985. High-Level Waste Preclosure Systems Safety Analysis Phase 1, Final Report, NUREG/CR-4303 (SAND85-7192), GA Technologies, Inc., San Diego, CA.

U. S. Nuclear Regulatory Commission. 1979. Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment, Regulatory Guide 4.15, Washington, DC.

U.S. Nuclear Regulatory Commission. 1984. NRC Review Plan: Quality Assurance Programs for Site Characterization of High-Level Nuclear Waste Repositories, Washington, DC.

U. S. Nuclear Regulatory Commission. 1985. Generic Technical Position on Waste Package Reliability Analysis, Washington, DC.

U. S. Nuclear Regulatory Commission. 1987. Generic Technical Position on Qualification of Existing Data for High-Level Nuclear Waste Repositories, Washington, DC.

8.0 BIBLIOGRAPHY

Tenera Corporation. 1985. Evaluation of the Waste Isolation Pilot Plant Classification of Systems, Structures and Components, EEG-30, Contract Report for the State of New Mexico, Berkeley, CA.

Nathwani, J.S. 1986. Safety Assessment of a Conceptual Design of a Facility for Geological Disposal of Candu Nuclear Fuel in the Canadian Shield, Paper presented at the International Atomic Energy Agency Symposium on the Siting, Design and Construction of Underground Repositories for Radiological Wastes, March 3-7, 1986, Hanover, Germany.

NUREG/CR-1278, Handbook on Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications, August 1983.

APPENDIX A
GLOSSARY

Accessible environment: (1) The atmosphere, (2) the land surfaces, (3) surface water, (4) oceans, and (5) the portion of the lithosphere that is outside the controlled area (10 CFR 60.2).

Activities: Deeds, actions, work, or performance of a specific function or task. In the HLW geologic repository program, the 10 CFR Part 60 Subpart G QA program applies to activities affecting the quality of all systems, structures, and components important to safety, and to the design and characterization of barriers important to waste isolation. These activities include: site characterization, facility and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities as they relate to items important to safety and barriers important to waste isolation (10 CFR 60.151). For example, the pertinent requirements of 10 CFR Part 50 Appendix B apply to all activities affecting the quality of structures, systems, and components important to safety and engineered barriers important to waste isolation. These activities include: designing (including such activities as safety analyses, laboratory testing of waste package materials to characterize their performance, and performance assessments), purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, and modifying. These types of activities do not need to be identified as part of the Q-list. However, activities related to natural barriers important to waste isolation should be identified and listed on a Quality Activities List. These activities include: performance assessments, site characterization testing, and activities that may impact the waste isolation capability of the natural barrier. For example, site characterization activities such as exploratory shaft construction, borehole drilling, and other activities that could physically or chemically alter properties of the natural barriers in an adverse way.

Barrier: Any material or structure that prevents or substantially delays movement of water or radionuclides (10 CFR 60.2).

Consequence analysis: A method by which the consequences of an event are calculated and expressed in some quantitative way, e.g., money loss, deaths, or quantities of radionuclides released to the accessible environment.

Containment: The confinement of radioactive waste within a designated boundary (10 CFR 60.2).

Credible event or credible accident: An event or accident scenario which needs to be considered in the design of a geologic repository.

Engineered barrier system: The waste packages and the underground facility (10 CFR 60.2). The maximum radionuclide release rate is measured at this boundary (10 CFR 60.113(a)(1)(ii)(B)). Geologic repository: A system which is intended to be used for, or may be used for, the disposal of radioactive wastes in excavated geologic media. A geologic repository includes: (1) the geologic repository operations area, and (2) the portion of the geologic setting that provides isolation of the radioactive waste (10 CFR 60.2).

Geologic repository operations area: A high-level radioactive waste facility that is part of a geologic repository, including both surface and subsurface areas, where waste handling activities are conducted (10 CFR 60.2).

Items important to safety: Those engineered structures, systems, and components essential to the prevention or mitigation of an accident that could result in a radiation dose to the whole body, or any organ, of 0.5 rem or greater at or beyond the nearest boundary of the unrestricted area at any time until the completion of permanent closure (10 CFR 60.2).

Items important to waste isolation: Natural and engineered barriers which are relied on for achieving the postclosure performance objectives in 10 CFR 60 Subpart E.

Non-mechanistic failures: Postulated failures which are not based on previously observed modes or mechanisms but which are assumed to provide conservatism in safety assessments.

Performance allocation: This term applies to the process of deriving subsystem and component performance goals from performance objectives. A systematic process of assigning confidence levels with their desired, associated performance goals for the mined geologic disposal systems, subsystems, and components.

Performance assessment: The process of quantitatively evaluating component and system behavior, relative to containment and isolation of radioactive waste, to determine compliance with the numerical criteria associated with 10 CFR Part 60.

Performance confirmation: The program of tests, experiments, and analyses which is conducted to evaluate the accuracy and adequacy of the information used to determine with reasonable assurance that the performance objectives for the period after permanent closure will be met (10 CFR 60.2).

Q-list: In the geologic repository program, a list of structures, systems, and components important to safety, and engineered barriers important to waste isolation that must be covered under the QA requirements of 10 CFR 60 Subpart G.

Qualification Testing: Demonstration that an item meets design requirements.

Quality Activities List: In the geologic repository program, a list of those major activities conducted during site characterization, construction, operation, or closure that relate to natural barriers important to waste isolation. These activities, which must be covered under the 10 CFR Part 60 Subpart G QA program, include data gathering, performance assessments, and those activities that could affect a natural barrier's ability to isolate waste.

Quality assurance: Those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its subsystems or components will perform satisfactorily in service. Quality assurance includes quality control, as defined below.

Quality control: Those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, system, structure, or component to predetermined requirements (10 CFR 60.150).

Reliability analysis: An analysis that estimates the reliability of a system or component.

Scenario: An account or sequence of a projected course of action or event.

Site characterization: The program of exploration and research, both in the laboratory and in the field, undertaken to establish the geologic conditions and the ranges of those parameters of a particular site relevant to the procedures under this part. Site characterization includes borings, surface excavations, excavation of exploratory shafts, limited subsurface lateral excavations and borings, and in-situ testing at depth needed to determine the suitability of the site for a geologic repository, but does not include preliminary borings and geophysical testing needed to decide whether site characterization should be undertaken (10 CFR 60.2).

Site characterization plan: A general plan for site characterization activities for a candidate site for a high-level waste repository, as required in the Nuclear Waste Policy Act and 10 CFR Part 60.

Waste package: The waste form and any containers, shielding, packing and other absorbent materials immediately surrounding an individual waste container (10 CFR 60). The minimum waste package containment time is calculated at this boundary [10 CFR 60.113(a)(1)(II)(A)].

Unrestricted area: Any area, access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials, and any area used for residential quarters.

APPENDIX B

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This document provides guidance on how to identify items and activities subject to Quality Assurance in the high-level nuclear waste repository program for pre-closure and post-closure phases of the repository. In the pre-closure phase, structures, systems, and components essential to the prevention or mitigation of a accident that could result in an off-site radiation dose of 0.5rem or greater are termed "important to safety". In the post-closure phase, the barriers which are relied on to meet the containment and isolation requirements are defined as "important to waste isolation". These structures, systems, components, and barriers, and the activities related to their characterization, design, construction, and operation are required to meet quality assurance (QA) criteria to provide confidence in the performance of the geologic repository. The list of structures, systems, and components important to safety and engineered barriers important to waste isolation is referred to as the "Q-List" and lies within the scope of the QA program.

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APRIL 1988